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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/549,502 | 09/20/2006 | Youcef Fezoui | 277165US0PCT | 7750 |
| 22850 | 7590 | 03/03/2008 | | |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | EXAMINER GUDIBANDE, SATYANARAYAN R | |
| | | | ART UNIT 1654 | PAPER NUMBER |
| | | | NOTIFICATION DATE 03/03/2008 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | |
|------------------------------|--|--------------------------------------|
| Office Action Summary | Application No. 10/549,502 | Applicant(s) FEZOUI ET AL. |
| | Examiner SATYANARAYANA R. GUDIBANDE | Art Unit 1654 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 2-10, 12-16 and 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/13/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I invention and SEQ ID NO: 3 as species in the reply filed on 12/20/07 is acknowledged.

A search for SEQ ID NO: 3, Xaa Phe Gly Ala Pro Xaa, where in Xaa can be any naturally occurring amino acid (Sequence listing filed 9/20/06, page 1 and 2) indicated that the SEQ ID NO: 3 is not free of art.

Claims 1-20 are pending.

Claims 2-10 and 20 have been withdrawn from further consideration as being drawn to non-elected species. The art was found on SEQ ID NO: 3. Sequence found in the prior art becomes the elected species and the claims 2-10 and 20 does not read on the species found in the prior art, for e.g., claim 2 requires that X2 and X3 to be Aspartic acid. The prior art sequence corresponding to SEQ ID NO: 3 do not have an Aspartic acid at position X3 and hence does not read on the elected species. See MPEP 803.02 "[I]n the case of an application with a Markush-type claim drawn to the compound X-R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, XA, XB, XC, XD, or XE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration".

Claims 12-16, 18 and 19 have been withdrawn from further consideration as being drawn to non-elected invention.

Claims 1, 11 and 17 are examined on the merit.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims are drawn to a peptide having an amino acid sequence of formula I (SEQ ID NO: 1):

$X_1FGAPX_2X_3$ in which

X_1 , is selected from Aspartic acid and a derivative thereof selected from acylated and alkylated Aspartic acid;

X_2 is Leucine or when X_3 is absent, X_2 is selected from Leucine and amidated Leucine;

X_3 is absent or selected from Aspartic acid and amidated Aspartic acid;
as well as salt and any derivative or analogue thereof.

Claim 1 as recited encompasses any and all peptides that are naturally occurring, because, it recites ‘as well as salts and any derivative or analogues of thereof’. Also, claim as recited does not indicate whether the peptide was isolated or synthesized. Therefore, any natural peptide comprising the motif ‘FGAP’ is encompassed by the claim and hence, the invention reads on non-statutory subject matter.

The motif “FGAP” is present in the following naturally occurring protein (amino acid sequence; complete genome structure of Mesorhizobium loti strain MAFF303099) as disclosed in the reference of Kaneko, et al., Proceedings of the International Congress on Nitrogen Fixation, 13th, Hamilton, ON, Canada, July 2-7, 2001 (2002). A copy of the STN search results containing the amino acid sequence of the protein that shows the ‘FGAP’ motif at position between 37 and 40 is supplied as a supplementary evidence to the cited reference.

1 MRTTKAGLRD FVTNNRHAIR LTVDSRAPMN PLRVSGLLKT YRRQVDNMQE
51 FIREADAVKH QMESVVDAFR HVLRIAAFRG LLQSNGFATP PSILMQNSPE
101 ARVKAGIGED RQISLPRVDE PLVEGICLEA LDMLNDFGAP LKIFGLLREV
151 VPGRQVEIVR LMLAMNRVEF RVARLLIELT PRSQLTNPLA RRKRYEGISP
201 AQMAAMEADI AEVSHDYLSA ASTHGSEMLN LIAATSYFDR LLNNPKLVRY
251 LARNFARQLE VFQNLLDFRE ARYKEHPPQA GS.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claim as presented does not recite a nature of the function for which these peptides are used. The claim as recited as afore-mentioned reads on all naturally occurring peptides having the motif ‘FGAP’.

Claim 1 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 11 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant application, applicants claim a peptide having an amino acid sequence of formula I (SEQ ID NO: 1):

$X_1FGAPX_2X_3$ in which

X_1 , is selected from Aspartic acid and a derivative thereof selected from acylated and alkylated Aspartic acid;

X_2 is Leucine or when X_3 is absent, X_2 is selected from Leucine and amidated Leucine;

X_3 is absent or selected from Aspartic acid and amidated Aspartic acid;
as well as salt and any derivative or analogue thereof.

Claim as recited encompasses any and all peptides having the motif 'FGAP'. The claim as recited is not supported by the specification as originally disclosed in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP clearly states that the purpose of the written description is to ensure that the inventor had possession of invention as of the filing date of the application, of the subject matter later claimed by him. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the application. These include, “level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed invention is sufficient” MPEP 2163.

In the instant application, applicants claim a peptide **having** the formula X1FGAPX2X3, as well as salt and **any derivative or analog thereof**. The claim as recited is not limited to a peptide as defined with variables X1, X2 and X3, but it encompasses innumerable peptides having the motif ‘FGAP’ including the naturally occurring peptides and the claim as recited does not provide a size limit on the peptide being claimed and hence encompasses larger peptides, polypeptide (proteins). Looking at the sequences from the conservative side with the size of a heptamer with 3 variables amino acids, wherein the three variable amino acids are any naturally occurring amino acids, the number of peptide possibilities are 4^{20} wherein the fourth amino acid

Art Unit: 1654

is the motif 'FGAP'. The number 4²⁰ does not include unnatural amino acids, derivatives and analogs. Therefore, the number of peptides encompassed by the instant claim as recited with any and all derivatives and analogs present in them is virtually limitless. The specification however, provides examples of following 10 peptide sequences:

| SEQ ID N°. | MW (g/mol) |
|------------|------------|
| 2 | 619 |
| 3 | 660 |
| 4 | 734 |
| 10 | 720 |
| 11 | 705 |
| 12 | 749 |
| 13 | 699 |
| 14 | 790 |
| 15 | 776 |
| 16 | 733 |

of which, only 1-3 and 11 has the required 'FGAP' motif present in the sequence. None of the examples of the peptides disclosed has any modification made to them (structure of the peptides have not been shown to indemnify modifications). Further, the sequence listing lists 17 peptides and only peptides with SEQ ID NOs: 1-3, 11 and 17 exhibits the required motif 'FGAP'. As result the SEQ ID NO: 4 that does not have the motif 'FGAP' recited in claim 11 falls outside the scope of the instant claim 1.

Therefore, the claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Moriarty, 1999, Biochemistry, 38, 1811-1818.

In the instant application, applicants claim a peptide having an amino acid sequence of formula I (SEQ ID NO: 1):

$X_1FGAPX_2X_3$ in which

X_1 is selected from Aspartic acid and a derivative thereof selected from acylated and alkylated Aspartic acid;

X_2 is Leucine or when X_3 is absent, X_2 is selected from Leucine and amidated Leucine;

X_3 is absent or selected from Aspartic acid and amidated Aspartic acid;
as well as salt and any derivative or analogue thereof.

The claim as recited has been interpreted as drawn to any peptide having the motif ‘FGAP’, because, the claims as recited is drawn to any derivative or any analog thereof.

The cited reference of Moriarty discloses the peptide I26P with the amino acid sequence ‘SNNFGAPLSS’ (page 1812, Figure 1, panel B). The highlighted portion of the cited peptide reads on the formula I of claim 1, SEQ ID NOs: 2 and 3 of the instant invention, wherein the X_1 is Asperagine (N). Since the claim as recited allows any derivatives and analogs, Asperagine of the cited reference is a derivative of Aspartic acid. In the cited reference the disclosed peptide ‘SNNFGAPLSS’ can be considered wherein the amino acid X_3 is missing. Therefore, the

Art Unit: 1654

hexapeptide **NFGAPL** of the cited reference meets the limitations of claims 1 and 11. The peptide of the cited reference have been purified in the presence of a buffer A consisted of water (page 1812, column 2, paragraph 1, under “Materials and Methods” section) and hence meets the limitation of claim 17 drawn to pharmaceutical composition comprising the peptide and a pharmaceutically acceptable carrier or excipient. The presence of peptide in an aqueous buffer meets the limitation of claim 17.

Therefore, the claims 1, 11 and 17 are anticipated by the cited reference of Moriarty.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/549,502
Art Unit: 1654

Page 10

/Satyanarayana R Gudibande/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654